DEC 16 2011

Attachment IV 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: K112819

1. Date of Submission: September 23, 2011

2. Sponsor
   Xiamen Double Engine Medical Material Co., Ltd.
   No.218, Houxiang Road, Haicang District, Xiamen, 361022, China

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   Position: General manager assistant
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3. Submission Correspondent
   Ms. Diana Hong & Mr. Lee Fu
   Mid-Link Consulting Co., Ltd
   P.O. Box 237-023, Shanghai, 200237, China
   Tel: +86-21-22815850
   Fax: 240-238-7587
   Email: info@mid-link.net

4. Proposed Device Identification

   Proposed Device Name: Reconstruction Locking Plate and 3.5mm Locking Screw

   Classification: II
   Product Code: HRS, HWC
   Regulation Number: 21 CFR 888.3030, 21 CFR 888.3040
   Review Panel: Orthopedic

   Intended Use Statement:
   The Reconstruction Locking Plate and 3.5mm Locking Screw are used together and intended to treat fractures of various bones, including the clavicle and pelvis.

5. Predicate Device Identification

510(k) Number: k092889
Product Name: Syntec Osteo – plate and screw Fixation
Manufacturer: Syntec Scientific Corporation

6. Device Description

The proposed devices of Reconstruction Locking Plate and 3.5mm Locking Screw are intended to treat fractures of various bones, including the clavicle and pelvis.

They are made of Titanium Alloy (Ti-6AL-4V), which meet ASTM F136, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications, which are widely used for surgical implants with well known biocompatibility.

The plates vary essentially through different lengths and number of plate holes. The screws are self-tapping with 3.5mm major diameter, which are applied with the reconstruction locking plates together.

The proposed devices are not provided sterile. It is required to be sterilized via autoclave method to reach a SAL of 10^{-6} by the hospital prior to surgery. The sterilization method is presented in the user manual, which was validated per ISO 17665-1: 2006 Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.

7. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ASTM F 382-99, Standard Specification and Test Method for Metallic Bone Plates
ASTM F 543-07, Standard Specification and Test Methods for Metallic Medical Bone Screws

8. Substantially Equivalent Conclusion

The proposed device, Reconstruction Locking Plate and 3.5mm Locking Screw, is determined to be Substantially Equivalent (SE) to the predicate device, Syntec Osteo – plate and screw Fixation, in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

DEC 16 2011

Xiamen Double Engine Medical Material Co., Ltd.
% Ms. Diana Hong & Mr. Lee Fu
Mid-Link Consulting Co., Ltd
P.O. Box 237-023
Shanghai, 200237, China

Re: K112819
Trade/Device Name: Reconstruction Locking Plate and 3.5mm Locking Screw
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliance and accessories
Regulatory Class: II
Product Code: HRS, HWC
Dated: September 23rd, 2011
Received: September 28th, 2011

Dear Ms. Hong:

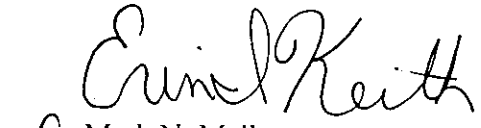
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112819

Section II Indications for Use

510(k) Number:

Device Name: Reconstruction Locking Plate and 3.5mm Locking Screw

Indications for Use:

The Reconstruction Locking Plate and 3.5mm Locking Screw are used together and intended to treat fractures of various bones, including the clavicle and pelvis.

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☐OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for (Division Sign-Off)
(Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K112819